

1.0



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,477	09/18/2003	David L. Evans	HO-P02228US1	8875
26271	7590	02/24/2006	EXAMINER	
FULBRIGHT & JAWORSKI, LLP 1301 MCKINNEY SUITE 5100 HOUSTON, TX 77010-3095			REIMERS, ANNETTE R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

10/666,477

Applicant(s)	
---------------------	--

EVANS ET AL.

Examiner

Annette R. Reimers

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Raab (U.S. Patent Number 4,281,420).

Raab discloses a prosthesis for implantation in a patient comprising a prosthesis body, 1, comprising a substrate material, wherein the prosthesis body comprises an implant portion for inserting into the body tissue of the patient, a bearing surface, 3, on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface, 2, comprising cross-linked polyethylene and adapted to cooperate with the bearing surface (see figures 1 and 2, column 6, lines 8-68 and column 7, lines 1-3). Furthermore, the prosthesis is capable of accommodating tissue in-growth on a portion of the prosthesis body.

Claims 7-8, 11 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Pope et al. (U.S. Patent Number 6,290,726).

Pope et al. teach a vertebral disc prosthesis comprising two prosthesis plates, 2051 and 2052, and a prosthesis core, 2053, wherein the prosthesis core cooperates with at least one prosthesis plate at surface permitting a rotational movement around a vertical axis and wherein the prosthesis can comprise at least one surface of cross-linked polyethylene and at least one component formed of zirconium or zirconium alloy (see figure 2Z, column 4, lines 42-53 and column 11, lines 13-39). Pope et al. further teaches an irregular textured surface structure, 234, that is adapted to accommodate tissue in-growth on a portion of the prosthesis (see alternative embodiment of Figure 2G and column 12, lines 25-34). In addition, the irregular surface structure comprises anchoring projections, 220a and 220b (see alternative embodiment of Figure 2I).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armini et al. (U.S. Patent No. 5,674,293) in view of Raab (U.S. Patent Number 4,281,420).

Armini et al. disclose a prosthesis for implantation in a patient comprising a prosthesis body comprising a substrate material, wherein the prosthesis body comprises an implant portion, 1, for inserting into the body tissue of the patient, a

Art Unit: 3733

bearing surface, 2, on the prosthesis body comprised of an abrasion resistant surface and a counter-bearing surface, 3, adapted to cooperate with the bearing surface and at least one component formed of zirconium or zirconium alloy and has at least one surface of blue-black or black oxidized zirconium (see figure 1, abstract, and column 4, lines 30-64) Furthermore, the prosthesis body further comprises at least one substrate layer having a depth-dependent variable concentration of zirconium (see column 4, lines 30-64). Moreover, the prosthesis is capable of accommodating tissue in-growth.

Armini et al. disclose the claimed invention except at least one surface being of cross-linked polyethylene. Raab discloses a prosthesis comprising cross-linked polyethylene and teaches that implants being made of chromium-cobalt-molybdenum alloy, stainless steel, titanium alloys and polymerized materials, such as UHMWPE have been successfully used to replace ends of long bones and joints (see column 1, lines 16-21). Raab further teaches the use of cross-linked polyethylene in order to increase the mechanical strength of the surface region, wherein a weak boundary layer is transformed into a strong boundary layer (see column 6, lines 60-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Armini et al. with cross-linked polyethylene, in view of Raab, as such would merely constitute a substitution of functionally equivalent structures. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Armini et al. with cross-linked polyethylene, in view of Raab, in order to increase the mechanical

Art Unit: 3733

strength of the surface region, such that a weak boundary layer is transformed into a strong boundary layer.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armini et al. (U.S. Patent No. 5,674,293).

Armini et al. disclose the claimed invention except for the surface of blue-black or black oxidized zirconium being from about 1 to 20 microns thick or from about 1 to 5 microns thick. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Armini with the surface of blue-black or black oxidized zirconium being from about 1 to 20 microns thick or from about 1 to 5 microns thick, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed on December 08, 2005 have been fully considered, but they are not persuasive. In response to applicant's argument that Raab does not teach or suggest a bearing surface, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. Kalman v. Kimberly Clark Corp., 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In addition, examiner respectfully disagrees with applicant regarding Raab lacking a bearing surface, since Raab does have a bearing surface, 3, comprising of an abrasion resistant surface that bears against the counter-bearing surface, 2. In addition, the bearing surface can also bear against human tissue. Furthermore, simply because something is a fixation surface does not mean that it cannot also be considered a bearing surface, i.e. the two terms can be synonymous.

In response to applicant's argument that Pope et al. does not teach or suggest a at least one surface of blue-black or black oxidized zirconium, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). In addition, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Furthermore, in response to applicant's argument that Pope et al. does not teach or suggest a at least one surface of blue-black or black oxidized zirconium, the limitations on which the Applicant relies (i.e., "the blue-black or black oxidized zirconium surface of the instant claims is a specific oxide composition that is distinct from passive oxides that form spontaneously in the presence of oxygen. The blue-black or black oxidized zirconium of the instant claims is formed only under certain conditions") are not stated in the claims. Therefore, it is irrelevant whether the reference includes those features or not.

In addition, examiner respectfully disagrees that Pope et al. teaches away from the use of cross-linked polyethylene. Pope et al. teach a preferred way, diamond-on-diamond bearing surface, to the claimed way. Moreover, Pope et al. teach that cross-linked polyethylene can be used for forming a bearing surface (see column 11, lines 13-39).

In response to applicant's argument that Armini et al. does not teach or suggest a bearing surface, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

In addition, examiner respectfully disagrees with applicant regarding Armini et al. lacking a bearing surface, since Armini et al. does have a bearing surface, 2, comprising of an abrasion resistant surface that bears against the counter-bearing surface, 3. In addition, the bearing surface can also bear against human tissue.

Furthermore, as previously stated, Armini et al. discloses the claimed invention except at least one surface being of cross-linked polyethylene. Raab discloses a prosthesis comprising cross-linked polyethylene and teaches that implants being made of chromium-cobalt-molybdenum alloy, stainless steel, titanium alloys and polymerized materials, such as UHMWPE have been successfully used to replace ends of long

Art Unit: 3733

bones and joints (see column 1, lines 16-21). Raab further teaches the use of cross-linked polyethylene in order to increase the mechanical strength of the surface region, wherein a weak boundary layer is transformed into a strong boundary layer (see column 6, lines 60-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Armini et al. with cross-linked polyethylene, in view of Raab, as such would merely constitute a substitution of functionally equivalent structures. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the prosthetic device of Armini et al. with cross-linked polyethylene, in view of Raab, in order to increase the mechanical strength of the surface region, such that a weak boundary layer is transformed into a strong boundary layer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

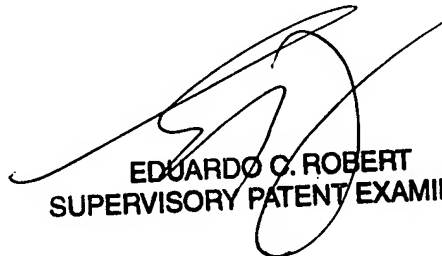
Art Unit: 3733

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER